



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Stamm et al**

Application No. **09/899,026**

Group Art Unit: **1615**

Filed: **July 6, 2001**

Examiner: **H. Sheikh**

For: **Fenofibrate Pharmaceutical Composition Having High Bioavailability and Method for Preparing It**

Docket No: 107664.115US3

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Request for Reconsideration under 37 CFR § 1.116

This Request for Reconsideration is submitted in reply to the final Office Action dated March 14, 2003, for which a response is due on or before July 13, 2003.

The Commissioner is authorized to charge the one month extension of time fee of \$110 to Deposit Account No. 08-0219. The Commissioner is authorized to charge any other necessary fees or credit any overpayments to Deposit Account No. 08-0219 to maintain the pendency of the application.

Claims 91, 99, 116, 119, 121, 122 and 124 are rejected under 35 USC § 102(b) as being anticipated by Boyer (US Patent No. 4,800,079).

Claims 92-98, 100-115, 117, 118, 120, 123 and 125-161 are rejected under 35 USC § 103 as being obvious over Boyer (US Patent No. 4,800,079) in view of Curtet et al (U.S. Patent No. 4,895,726).

In response to Applicants' Response filed November 6, 2002, the Examiner asserted:

The examiner and her primary examiner had made suggestions in the interview of 10/17/02 to provide a comparison of the dissolution rates of Boyer's product and the instant product using similar method, if possible. The applicant has not provided this information. The instant invention remains unpatentable over the prior art and therefore the rejection of claims 91-161 is maintained.

In response to the Examiner's suggestion in the Office Action, Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 by by Philippe Réginault (hereafter the Réginault Declaration) which shows that the presently claimed invention is not anticipated by and is unobvious over the cited references. As requested, the Réginault Declaration provides a direct comparison using the same method between the Boyer patent and the presently claimed invention.

It is known in the art that the composition described by Boyer is represented by Lipanthyl® 250. *See* Réginault Declaration at ¶ 7. The composition recited in the claims is represented in the specification at Example 2 and by Lipanthyl® Supra. *See* Réginault Declaration at ¶ 8.

A comparison of the dissolution profile of Boyer (i.e., Lipanthyl® 250) and the claimed invention (i.e., Lipanthyl® Supra) is shown in Tables 1 and 2 and Figures 1 and 2 in the Réginault Declaration at ¶ 11.

For the Examiner's convenience, the results described in the Réginault Declaration and shown in Example 2 and Figure 1 in the present application are reproduced in the Table below.

Time	% Dissolution recited in Pending Claims	% Dissolution of Lipanthyl® 250 corresponding to Boyer	% Dissolution of Lipanthyl® Supra corresponding to the Invention	% Dissolution of Inventive Example 2 in the Application
5 minutes	at least 10%	0.4%	26.8%	18.9%
10 minutes	at least 20%	0.8%	60.5%	67.1%
20 minutes	at least 50%	1.2%	83.0%	89.7%
30 minutes	at least 75%	1.9%	89.8%	95.9%

In comparing Boyer and the claimed invention, the Réginault Declaration, at ¶ 12, states:

The results shown above clearly demonstrate that Lipanthyl® 250 (i.e., U.S. Patent No. 4,800,079 to Boyer) and Lipanthyl® Supra (i.e., the above-identified application) have very different dissolution profiles — both for the extent and for the rate. Lipanthyl® Supra presented a complete dissolution of fenofibrate within 1 hour whereas Lipanthyl® 250 only released 4% fenofibrate (i.e., 10 mg) within 1 hour. Hence, the two formulations have a significantly different dissolution profiles.

Based on the results shown in the Réginault Declaration and the specification at Example 2, Applicants respectfully submit that the presently claimed invention has an unexpectedly superior dissolution profile when compared to Boyer. Accordingly, Boyer does not anticipate the presently claimed invention, and one skilled in the art would not arrive at the presently claimed invention based on the teachings in Boyer.

Curtet does not cure the deficiencies of Boyer. Curtet corresponds to EP-A-0330532 which is discussed in detail in the specification at page 2, lines 1-20 and Examples 2-4. Curtet corresponds to Lipanthyl® 200M in Figures 1 and 2 in the present application.

The dissolution medium and conditions in the present claims are a rotating blade method at 75 rpm, where the dissolution medium is water with 2% polysorbate 80 or 0.025 M sodium lauryl sulfate. In contrast, Curtet uses a rotating vane or continuous flow cell where the dissolution medium is water with 0.1 M sodium lauryl sulfate. The dissolution medium of Curtet comprises much more sodium lauryl sulfate (i.e., a surfactant) than the dissolution medium of the invention. Having more surfactant will necessarily enhance dissolution. Accordingly, it is necessary to compare the composition described in the Curtet reference and the claimed composition using the same method. This was done in the instant application.

Applicants have shown in Example 2 of the application that the presently claimed invention has an unexpectedly superior dissolution profile compared to Lipanthyl® 200M (i.e., the teachings in Curtet). Example 2 and Figure 1 in the application demonstrate that the claimed composition has an unexpectedly superior dissolution profile when compared to Lipanthyl® 200M as described by Curtet. For the Examiner's convenience, a comparison of the dissolution profile recited in the present claims with the dissolution profile of Curtet (i.e., Lipanthyl® 200M) is shown in the Table below.

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Time	% Dissolution Recited in Pending Claims	% Dissolution by Inventive Example shown in Example 2 of the Application	% Dissolution by Curtet as Lipanthyl® 200M shown in Example 2 of the Application
5 minutes	at least 10%	18.9%	0%
10 minutes	at least 20%	67.1%	3.7%
20 minutes	at least 50%	89.7%	31.2%
30 minutes	at least 75%	95.9%	54.9%

As shown from the summary above, Example 2 and Figure 1 in the application demonstrate that Curtet does not have a dissolution profile like the presently claimed dissolution profile.

Applicants respectfully submit that Curtet does not disclose or suggest a composition having the presently claimed dissolution profile, and that Curtet provides no motivation or suggestion to achieve the presently claimed dissolution profile.

In view of the above, Applicants respectfully submit that Boyer does not anticipate the presently claimed invention, and that Boyer in view of Curtet does not render the presently claimed invention obvious. Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. §§ 102 and 103 be withdrawn.

An early and favorable reconsideration and allowance of claims 91-161 is respectfully requested. Examiner Sheikh is encouraged to contact the undersigned to expedite prosecution of this application.

Respectfully submitted,

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Date: July 8, 2003
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